

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9159

Bartle, J.

October 30, 2013

Dorothy L. Wilson ("Ms. Wilson" or "claimant"), a class member under the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Ralph W. Purdun, Ms. Wilson's son, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Michael S. Mancina, M.D. Based on an echocardiogram dated December 14, 2001, Dr. Mancina attested in Part II of Ms. Wilson's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.⁴ Based on

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Dr. Mancina also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

such findings, claimant would be entitled to Matrix A-1, Level II⁵ benefits in the amount of \$471,345.⁶

In the report of claimant's echocardiogram, Dr. Mancina indicated that claimant had "[m]oderate mitral valve regurgitation by Phen-Fen criteria with eccentric jet and 20% of the left atrium occupied by regurgitant flow during systole." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2006, the Trust forwarded the claim for review by Noyan Gokce, M.D., one of its auditing cardiologists. In audit, Dr. Gokce concluded that there was no reasonable medical basis for Dr. Mancina's finding that claimant had moderate mitral regurgitation because her echocardiogram

5. In her Green Form, claimant requested Matrix Benefits at Level IV. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant does not contest, that she only alleged conditions consistent with a claim for Level II benefits.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal atrial dimension, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Gokce stated:

In my opinion, [mitral regurgitation] appears mild. The mitral RJA traced in the videotape appears fairly accurate and is indicated as 2.5 cm². My tracing of mitral RJA was also similar at 2.44 cm². However, the left atrial area in the videotape is traced inaccurately and markedly underestimates the true [left atrial] area. The tracing provided of the [left atrium] does not track the true [left atrial] wall borders in the apical view, and is traced loosely within the actual [left atrial] cavity. My tracing of end-systolic [left atrial] area in the same view was 19.5 cm². This provides a mitral RJA/LAA ratio of 12.5%, most consistent with mild [mitral regurgitation].

Based on Dr. Gokce's finding that claimant had only mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Wilson's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant submitted a November 3, 2006 echocardiogram and report along with reports for echocardiograms dated July 22, 2003 and July 15, 2004, each of which indicated that claimant suffered from moderate mitral regurgitation. Claimant contended that these reports confirm the attesting physician's representation of

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Wilson's claim.

moderate mitral regurgitation. Ms. Wilson also submitted a letter from Dr. Mancina, which stated, in relevant part:

I am submitting new information but it does confirm my original opinion that Ms. Wilson does have moderate mitral valve regurgitation.

....

There are at least three cardiologists who have seen this patient since her original application for trust benefits that in their clinical opinions have stated that Ms. Wilson does have moderate mitral valve regurgitation. In spite of what the Trust auditors have said, in 2006 there is clear evidence that there is moderate mitral valve regurgitation which supports what we saw when we submitted Ms. Wilson's original echocardiogram.

....

I submit that the patient has moderate mitral valve regurgitation by both clinical and Phen-Fen criteria in 2006 as stated in our previous submissions....

The Trust then issued a final post-audit determination, again denying Ms. Wilson's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Wilson's claim should be paid. On April 12, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7112 (Apr. 12, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust did not reply. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D. F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b) .

In support of her claim, Ms. Wilson asserts that she should prevail on her claim because the attesting physician's finding of moderate mitral regurgitation was confirmed by three separate cardiologists in three subsequent echocardiograms. Claimant also asserts that the dispute between the attesting physician and the auditing cardiologist is merely a difference of opinion due to inter-reader variability and that "[a]ll the opinions are correct because they are within the range of reasonable interpretation." Finally, claimant argues that the auditing cardiologist failed to apply properly the reasonable medical basis standard because he simply "substituted his judgment for that of the attesting doctor, an impermissible overstepping of his authority."

The Technical Advisor, Dr. Vigilante, reviewed claimant's December 14, 2001 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Wilson had moderate mitral regurgitation. Specifically, Dr. Vigilante observed, in relevant part:

Visually, there was, at most, mild mitral regurgitation noted in the apical four chamber view. I digitized the cardiac cycles in the apical four chamber view in which the mitral regurgitant jet could be evaluated. I

measured the RJA in multiple cardiac cycles. I also measured the largest LAA in the apical four chamber view. The largest representative RJA in the apical four chamber view was 1.8 cm². The LAA in the apical four chamber view measured 22.5 cm². Therefore, the largest RJA/LAA ratio in the apical four chamber view was 8% qualifying for mild mitral regurgitation. The RJA/LAA ratio never came close to approaching 20%. There was no evaluation of the mitral regurgitant jet in the apical two chamber view. The sonographer obtained an RJA of 2.5 cm². This was an inaccurate measurement as it included low velocity, non-mitral regurgitant flow. In addition, the sonographer obtained a LAA of 15.47 cm² in the apical four chamber view. This was an inaccurate measurement and did not include the lateral, posterior, and medial aspects of the left atrium. An LAA measurement of 15.47 cm² would not be consistent with left atrial enlargement. Indeed, the left atrium was enlarged.

....

... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the two submitted studies show mild mitral regurgitation with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on these studies even taking into account inter-reader variability.⁹

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, we disagree with claimant that there is a reasonable medical basis for Dr. Mancina's representation that Ms. Wilson's December 14, 2001 echocardiogram demonstrates moderate mitral

9. Dr. Vigilante also reviewed claimant's November 3, 2006 echocardiogram and concluded that it also demonstrated only mild regurgitation.

regurgitation. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of the Settlement Agreement and the Audit Rules leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. As we previously explained, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Gokce determined in audit that the LAA in claimant's December 14, 2001 echocardiogram "is traced inaccurately and markedly underestimates the true [LAA] ." Specifically, he explained, "The tracing provided of the [left atrium] does not track the true [left atrial] wall borders in the apical view, and is traced loosely within the actual [left atrial] cavity."¹⁰ Dr. Vigilante similarly concluded that the

10. Thus, we reject claimant's assertions that the auditing cardiologist did not properly apply the reasonable medical basis standard and simply substituted his judgment for that of the
(continued...)

sonographer obtained "an inaccurate measurement [of the LAA] and did not include the lateral, posterior, and medial aspects of the left atrium." In addition, Dr. Vigilante determined that the measurement obtained by the sonographer of claimant's RJA "was an inaccurate measurement as it included low velocity, non-mitral regurgitant flow."¹¹ Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis of moderate mitral regurgitation. To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.¹²

Finally, we reject claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that she had moderate mitral regurgitation. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, a finding of moderate mitral regurgitation cannot be

10. (...continued)
attesting physician.

11. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

12. For these reasons as well, we disagree with claimant that there is a reasonable medical basis for Dr. Mancina's representation of moderate mitral regurgitation based on Ms. Wilson's December 14, 2001 echocardiogram simply because multiple cardiologists concluded that she had moderate mitral regurgitation based on studies performed years after her echocardiogram of attestation.

medically reasonable here. The auditing cardiologist and the Technical Advisor concluded, and claimant did not adequately dispute, that Ms. Wilson's December 14, 2001 echocardiogram demonstrated at most mild mitral regurgitation and that the attesting physician's representation of moderate mitral regurgitation was based on inaccurate measurements and improper tracing resulting in an inflated level of moderate mitral regurgitation. Adopting claimant's argument regarding inter-reader variability would allow a claimant who did not have the requisite level of mitral regurgitation to recover benefits and would render meaningless this critical provision of the Settlement Agreement.¹³

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Wilson's claim for Matrix Benefits and the related derivative claim submitted by her son.

13. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on these studies even taking into account inter-reader variability."